

(f) If formaldehyde is used as the inactivating agent and the serial has not been found satisfactory by the viricidal activity test, bulk or final container samples of completed product from each serial shall be tested for residual free formaldehyde content using the Basic Fuchsin Test.

(1) The residual free formaldehyde content of biological products containing Clostridial antigens shall not exceed the equivalent of 0.5 percent formaldehyde solution (1,850 parts per million formaldehyde.)

(2) The residual free formaldehyde content of bacterins, bacterin-toxoids, and toxoids other than those containing Clostridial antigens, shall not exceed the equivalent of 0.2 percent formaldehyde solution (740 parts per million formaldehyde.)

[39 FR 16862, May 10, 1974. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 60 FR 14355, Mar. 17, 1995]

§ 113.101 *Leptospira Pomona* Bacterin.

Leptospira Pomona Bacterin shall be produced from a culture of *Leptospira pomona* which has been inactivated and is nontoxic. Each serial of biological product containing *Leptospira pomona* fraction shall meet the applicable requirements in § 113.100 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product shall be diluted with physiological saline so that each 0.25 ml contains not more than 1/800th of the dose recommended on the label and shall be tested for potency, using the two-stage test provided in this paragraph.

(1) *Vaccinates.* Inject each of at least 10 but not more than 12 young adult hamsters, each weighing 50 to 90 grams, with 0.25 ml of the diluted bacterin either subcutaneously or

intramuscularly, in accordance with the label recommendations for use.

(2) *Controls.* Retain at least 10 but not more than 12 additional hamsters from the same group as unvaccinated controls.

(3) *Challenge.* From 14 to 18 days postvaccination, challenge each of 10 vaccinates and each of 10 controls intraperitoneally with a suspension of virulent *Leptospira pomona* organisms, using a dose of 10–10,000 hamster LD₅₀ as determined by titration.

(4) *Post-challenge period.* Observe the vaccinates and controls for 14 days post-challenge and record all deaths. If eight or more controls die of leptospirosis, the test is valid and the results shall be evaluated according to the following table:

| Stage | Number of vaccinates | Cumulative number of vaccinates | Cumulative total dead hamsters for satisfactory serial | Cumulative total dead hamsters for unsatisfactory serial |
|---------|----------------------|---------------------------------|--|--|
| 1 | 10 | 10 | 2 or less | 5 or more. |
| 2 | 10 | 20 | 5 or less | 6 or more. |

(5) If three or four vaccinates die in the first stage, the second stage shall be conducted in a manner identical to the first stage.

(6) If the second stage is used, each serial shall be evaluated according to the second part of the table. On the basis of cumulative results, each serial shall either pass or fail.

[39 FR 16862, May 10, 1974, as amended at 40 FR 20067, May 8, 1975; 45 FR 40100, June 13, 1980. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 66785, Dec. 26, 1991]

§ 113.102 *Leptospira Icterohaemorrhagiae* Bacterin.

Leptospira Icterohaemorrhagiae Bacterin shall be produced from a culture of *Leptospira icterohaemorrhagiae* which has been inactivated and is nontoxic. Each serial of biological product containing *Leptospira icterohaemorrhagiae* fraction shall meet the applicable requirements in § 113.100 and be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested